Department of Mental Health and Addiction Services Institutional Review Board - Office of the Commissioner Quality Management and Improvement 410 Capitol Avenue MS # 14 PO Box 341431 Hartford, CT 06134

REPORT OF STUDY RELATED COMPLAINT

Please complete form electronically, print out and submit signed copy. Report may be forwarded to the IRB chair electronically but must be followed by a signed hard copy.

Date of report:	
Title of study:	
DMHAS Study ID Number:	
Principal investigator Name and Title: Phone: Fax: E-mail:	
Data of complaints	Data investigates became average
Date of complaint:	Date investigator became aware of complaint:
Study site involved:	complaint.
•	
Description of complaint:	
Where applicable, please describe action taken to ameliorate any discomfort or negative consequence related to the complaint:	
Where applicable, please describe acrecurrence:	tion taken to reduce/eliminate likelihood of
Does the nature of the complaint suggestions of the complaint suggestions of the complaint suggestions. □ yes □ no	gest/require a change in study protocol and/or
Description of any action planned or to procedural change; intervention with protocol change; etc:	taken as a result of complaint such as internal research staff; consent form change;
Is IRB approval of a revision required ☐ yes ☐ no	with relation to any proposed changes?
Principal Investigator – Signature	Date
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